K050994

CardinalHealth

AUG 3 2005

Cardinal Health
1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System

Sponsor:	Cardinal Health 1430 Waukegan Road MPWM McGaw Park, IL 60085
Regulatory Affairs Contact:	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	April 2005
Common Name:	Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System
Classification:	Class II per 21CFR §868.5905
Predicate Device:	EME Infant Flow System
Description:	The Cardinal infant nCPAP system consists of a Generator, Prongs, Masks, and a headgear/fixation device. A driver (hardware) delivers a mixture of air and oxygen to provide the prescribed level of CPAP through a circuit and generator. Either a prong or mask is attached to the generator as a patient interface. The generator is held to the infant's nose by straps connected to a headgear/fixation device. This product is a single patient use, non-sterile prescriptive device.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System

Intended Use:	This device, consisting of a generator, prongs, masks and a headgear/fixation device, is intended to provide continuous positive airway pressure to newborns and infants with compromised respiratory systems while in a hospital environment.
Substantial Equivalence:	Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System is substantially equivalent to the EME Infant Flow System in that: - the intended use is the same - the performance attributes are similar
Summary of testing:	All materials used in the fabrication of the Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 - 2005

Ms. Sharon Nichols
Regulatory Affairs Manager
Cardinal Health
1430 Waukegan Road, Building KB
McGraw Park, Illinois 60085

Re: K050994
Trade/Device Name: Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 7, 2005
Received: July 8, 2005

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

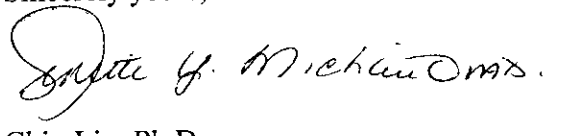
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):	K050994
Device Name:	Airlife Infant Nasal Continuous Positive Airway Pressure (nCPAP) System
Indications for Use:	This device, consisting of a generator, prongs, masks and a headgear/fixation device is intended to provide continuous positive airway pressure to newborns and infants with compromised respiratory systems while in a hospital environment.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050994